conducted throughout the State of Florida.

Board of Governors of the Federal Reserve System, May 13, 1997.

**Jennifer J. Johnson,**

*Deputy Secretary of the Board.*

[FR Doc. 97–12991 Filed 5–16–97; 8:45 am]

**BILLING CODE 6210–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

### Agency Information Collection Activities: Submission for Office of Management and Budget (OMB) Review; Comment Request

*Title*: Performance (Progress) Reports for Title IV Training, Research, and Discretionary Projects and Programs Grantees

*Description*: Project performance reports provide an understanding of how projects funded by Title IV of the Older Americans Act are being administered by grantees, in conformance with legislative requirements, pertinent federal regulations, and other applicable instructions and guidelines issued by the Administration on Aging (AoA). This information will be used for federal oversight of the Title IV Training, Research, and Discretionary Projects and Programs.

*Respondents*: Applicants who have been awarded Title IV grants.

*Annual Burden Estimates*:

| Instrument | Number of respondents | Average number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Performance Report for Title IV Grantees | 75 | 2 | 16 | 2400 |

*Additional Information*: Copies of the collection may be obtained by writing to the Administration on Aging, Office of the Executive Secretariat, 330 Independence Avenue, S.W., Washington, DC 20201, Attn.: AoA Reports Clearance Officer.

*OMB Comment*: OMB is required to make a decision, concerning the collection of information, between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 60 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, DC 20503, Attn.: Ms. Wendy Taylor.

Dated: May 8, 1997.

**William F. Benson,**

*Acting Principal Deputy, Assistant Secretary for Aging.*

[FR Doc. 97–10384 Filed 5–16–97; 8:45 am]

**BILLING CODE 4150–04–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97M–0185]**

### ELA Medical, Inc.; Premarket Approval of Chorus RM Model 7034 DDDR Pacemaker System and Opus RM Model 4534 SSIR Pacemaker System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its approval of the application submitted by ELA Medical, Inc., Plymouth, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Chorus RM Model 7034 DDDR Pacemaker System and Opus RM Model 4534 SSIR Pacemaker System. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 10, 1997, of the approval of the application.

**DATES:** Petitions for administrative review by June 18, 1997.

**ADDRESSES:** Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Marian Kroen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

**SUPPLEMENTARY INFORMATION:** On January 18, 1996, ELA Medical, Inc., Plymouth, MN 55441, submitted to CDRH an application for premarket approval of Chorus RM Model 7034 DDDR Pacemaker System and Opus RM Model 4534 SSIR Pacemaker System which includes an IBM compatible microcomputer which has been configured and furnished by ELA Medical, Inc., with CSO 2.46 programming software and is connected to a CPR1 programming lead. These devices are implantable cardiac pacemakers and are indicated for: (1) Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in minute ventilation; (2) The generally accepted patient conditions warranting chronic cardiac pacing which include:

- Symptomatic paroxysmal or permanent second or third-degree AV block;
- Symptomatic bilateral bundle branch block;
- Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders;
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; and
- Vaso-vagal syndromes or hypersensitive carotid sinus syndromes.

The Chorus RM is also indicated for dual-chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output; and
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

In accordance with the provisions of section 515(c)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially